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April 23, 1998

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**OFFICE OF PETITIONS
DEPUTY A/C PATENTS**

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Re: **U.S. Patent Application Serial No. TBA**
For: **CHIMERIC EMBRYOS AND ANIMALS
CONTAINING HUMAN CELLS**
Filed: **December 18, 1997**
Our Reference No. **45010-00601**

Dear Sir:

04/28/1998 MCAERO 00000041 08993564

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Submitted herewith is a Supplemental Petition Under 37 C.F.R. 1.182 with Exhibit A together with a law firm check in the amount of \$130.00. The Commissioner is hereby authorized to charge any additional fees due, or credit any overpayment to Deposit Account 03-2469.

Also enclosed please find a postcard indicating the documents being filed. Please date-stamp the card indicating receipt of the attached papers and return it to us.

Respectfully Submitted,

Patrick J. Coyne
PATRICK J. COYNE, Reg. No. 31,821
DAVID R. YOHANNAN, Reg. No. 37,480

Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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OFFICE OF PETITIONS
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In re
Application of: STUART A. NEWMAN
Serial No.: 08/993,564
Filed: December 18, 1997
For: CHIMERIC EMBRYOS AND ANIMALS CONTAINING HUMAN
CELLS
Atty. Docket #: 45010-00601

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Supplemental Petition Under 37 C.F.R. 1.182

Applicant Dr. Stuart Newman, and co-owners Dr. Stuart Newman and The Foundation on Economic Trends, respectfully submit this Supplemental Petition to the Commissioner, requesting clarification of the Office's current interpretation, regulatory guidance, and policies with respect to the patenting of living organisms.

Applicant has applied for a patent for an invention entitled Chimeric Embryos and Animals Containing Human Cells, Serial No. 08/993,564. In discussions of the application with third parties, the application has received some media attention, including a segment on ABC World News Tonight with Peter Jennings on Thursday, April 2, 1998, and articles in the journal Nature and the Washington Post. In response to this publicity, the Commissioner issued a



document entitled "Media Advisory" on April 2, 1998. A copy of the Commissioner's Media Advisory is attached as Exhibit A.

Applicant is concerned regarding the Commissioner's response of issuing a Media Advisory for several reasons. First, applicant is unaware of any other situation in which the Commissioner has issued a press release specifically directed to a pending application. Moreover, Applicant is concerned that the issuance of a press release, as well as any external, or even internal statements by the Commissioner within the Patent and Trademark Office, commenting on the pending case could have a chilling effect on the fair and objective consideration of the patentability of the application. The right of confidentiality of patent applications is a right that belongs to the applicant, not to the Office. Although Applicant respectfully acknowledges that the Commissioner may have felt compelled to speak publicly on this topic in view of the disclosures by the Applicant, Applicant respectfully submits that Applicant's public disclosure does not provide a justification for the Office to issue statements that may be construed as potentially prejudging decisions regarding the patentability of the invention.

Second, Applicant is concerned regarding the authority cited in the Commissioner's statement to the effect that the Office has authority to reject applications on moral grounds. Applicant respectfully submits that the case cited by the Commissioner in the Media Advisory does not support that proposition.

Applicant acknowledges that prior to the passage of the current Patent Act in 1952, judicial authority vested with the Patent Office discretion to reject applications on moral grounds.

Applicant understands that a number of applications were rejected prior to passage of the 1952 Act, on moral grounds.

Nonetheless, the 1952 Act, under which the Patent Office currently operates, contains no provision or authority for the Commissioner to reject an application on moral grounds. Applicant is unaware of any situation in which the Commissioner has ever rejected an application on moral grounds under the 1952 Act.

Third, Applicant is concerned regarding the use of any such "moral grounds" as a criteria for patentability under the utility requirement. The stated utility of the present application -- for use as a medical research model, in areas including, but not limited to, drug testing, organ transplantation and related studies, toxicity studies and cell biology and cell development research -- is clearly beneficial. Regardless of how the merits of the utility of the present application are viewed, its utility is certainly no less than that of numerous patents that have been issued for transgenic animals containing human material. Indeed, patent applications are currently pending or have been granted for a range of transgenic animals containing human genes, chromosomes, cells, tissues, and organs. Is it now the position of the Patent & Trademark Office that any animal containing human biological material might "fail to meet the public policy and morality aspects of the utility requirement?" Does the Office have some formal or informal regulatory guidance as to what kind and how much human genetic or other human biological material transferred to another animal -- for which a patent is being sought -- is unacceptable on "moral" grounds?

Perhaps more important, any standard such as "moral grounds" is inherently subjective. Providing the discretion to make determinations as to patentability on such inherently subjective

grounds leads to inconsistent results and a lack of uniformity in decisionmaking. Worse yet, it may lead to arbitrary and inconsistent decisions by the U.S. Patent and Trademark Office, with one Examiner considering objectionable what another considers beneficial to mankind. Accordingly, even with extensive guidelines, which the Patent Office currently lacks in this area, the problem of inconsistent decisionmaking remains.

Conclusion

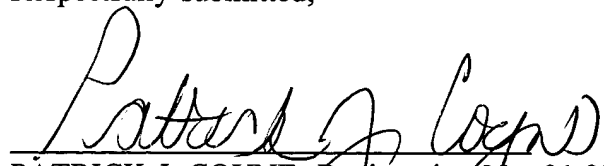
For the foregoing reasons, Applicant respectfully requests:

- (1) that the Commissioner identify the statutory and judicial authority that supports the Commissioner's statement that the Office does in fact have the right to refuse patentability of an invention on "moral grounds";
- (2) that the Commissioner identify any guidance that the Patent Office has provided in the form of Federal regulations on the patentability of life forms or on the acceptable parameters for inventions claiming life forms that may be patentable;
- (3) that the Commissioner identify any guidance that the Patent Office has provided in the form of policies, guidelines, procedures (including but not limited to the Manual of Patent Examining Procedure) on these issues; and
- (4) to the extent that the Patent Office has not provided guidance on these issues, that the Patent Office provide such guidance, either through formal or informal rulemaking, or such other procedures as the Commissioner deems appropriate, on acceptable subject matter for the patentability of life forms claimed as inventions,

and in particular, on the patentability of life forms claimed as inventions that comprise human genes, chromosomes, cells, tissues, organs, or other human biological products.

Respectfully submitted,

Dated: April 24, 1998


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